EPA Sets New Policy on Pesticide Cancer Risks

It plans to permit some weak carcinogens while banning higher risk products: a questionable reinterpretation of Delaney?

THE ENVIRONMENTAL PROTECTION AGENCY (EPA) announced last week that it is adopting a controversial change in the way it regulates pesticides suspected of causing cancer. The new policy would permit the use of some weakly carcinogenic compounds that previously have been banned, but it could result in removal from the market of other products that have been in use for decades. The change, EPA believes, will lower the overall cancer risk from pesticide residues in food.

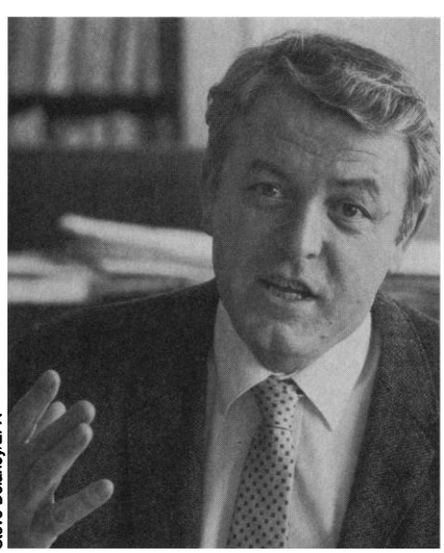
But, in adopting the new policy, EPA is skating on thin legal ice. It appears to be proposing a flexible interpretation of one of the most unbending provisions in the nation's food laws—the infamous Delaney clause in the food and drug act, which prohibits the addition to processed foods of any compound that causes cancer in test animals. The Delaney clause has kept several new pesticides off the market when residues are likely to be present at any level in processed food. Now, EPA is arguing that the clause need not be invoked if the residues pose a negligible cancer risk.

John A. Moore, EPA's acting deputy administrator, acknowledged last week that there is "some legal risk" in the new approach. But he argued that it is a "common sense" policy that will permit low-risk pesticides to replace more hazardous compounds. Not surprisingly, that viewpoint is not universally shared. "It is not legal for EPA to modify a specific provision in the law, which has been in effect for two decades," says Janet Hathaway of the Natural Resources Defense Council, an environmentalist group.

Nobody denies that EPA is facing a tough problem in dealing with the Delaney clause. New toxicological data indicate that many existing pesticides could be carcinogenic, and new detection techniques make it possible to pick up trace amounts of these compounds in food. According to EPA's own analysis, about 40 different compounds that are suspected of being carcinogens leave residues in processed foods. Many of them have large markets and important uses, but under a strict interpretation of the Delaney clause, they should be banned.

The agency has been aware for some time that these products are potentially in violation of the law, but it has not so far invoked the Delaney clause to remove a single "old" pesticide from the market. In contrast, since new test procedures were required in 1978, it has been applying the clause rigorously in its review of new pesticides. As a result, many new compounds have not been approved, even when the cancer risk they pose is small. Consequently, most of the existing cancer risk from pesticides in processed foods stems from compounds approved before 1978.

Under its new policy, EPA intends to apply a uniform standard to both new and old pesticides. It would permit their use only if they leave residues in processed food that pose a cancer risk from a lifetime's exposure of less than one in a million. Although Moore acknowledges that the one-in-a-million standard is somewhat arbitrary, he notes that it is the point at which the risk has traditionally been recognized as "negligible." By declining to apply the Delaney clause to remove a negligible risk, EPA is invoking a so-called *de minimis* doctrine that holds that regulatory agencies need not apply a law in its literal sense if to do so would be counterproductive.



Steve Delaney/EPA

John Moore: *The new policy has "some legal risk, but represents "common sense."*

The change would not only treat old and new pesticides in the same way but it would also do away with some inconsistency in the regulation of pesticide residues in raw and processed foods. The Delaney clause applies only to processed foods, not raw agricultural products. EPA has thus been able to permit weakly carcinogenic pesticides to be used even when residues are present in raw agricultural products, but in theory it is supposed to ban uses of these compounds if the residues persist when the foods are processed. In public health terms, the dual standard makes no sense.

EPA now intends to apply the one-in-a-million risk criterion to all pesticide uses, regardless of whether the residues are present in raw or processed foods. A lower risk would prompt no action. A higher risk would cause the Delaney clause to kick in for processed foods, and a cost-benefit analysis would be done if the residues are present only in raw products.

This approach was recommended last year by an influential report by a committee of the National Academy of Sciences (*Science*, 29 May 1987, p. 1054). The committee urged the adoption of the one-in-a-million "negligible risk" approach for all pesticide uses. It pointed out that the overall lifetime cancer risk in the United States is now about one in four, or 0.25. Adoption of the negligible risk standard for pesticides would raise the risk to 0.250001.

According to Charles Benbrook, the executive director of the Academy's Board on Agriculture, the report contained an "implicit compromise" that a small new risk could be permitted by dropping a rigid interpretation of the Delaney clause for new pesticides "if EPA moves aggressively to remove those old pesticides that represent the bulk of the risks." The committee in fact estimated that 90% of the total cancer risk from pesticides in the diet comes from old compounds. Benbrook faults EPA's new policy for not moving aggressively enough on the old high-risk compounds, however. "They have taken only half a bite of the apple," he says.

EPA intends to apply its new policy to existing pesticides on a case-by-case basis. That will require a complex legal processes for each pesticide and could take years. At the same time, it will review about a dozen new pesticides under the negligible risk standard.

Benbrook argues, however that a more generic approach should be used. EPA, he says, should simply list in the *Federal Register* those pesticide uses that are in violation of the negligible risk standard and inform the manufacturers that they would have 18

months to bring their products into compliance or the registrations would be canceled. "That is the approach we were kind of expecting," he says.

EPA spokesman Al Heier acknowledges that EPA has the authority to move against the old pesticides in this way, but the agency "intends to do it as accurately as possible," he says. "The process we are using is a good process, but it's slow," Heier contends.

EPA's new policy faces potential legal and legislative challenges. Hathaway of the Natural Resources Defense Council says that her group may consider taking the agency to court, but until EPA takes its first action under the new policy there may be no legal basis for a challenge. She says she is particularly disturbed because the new policy "does not guarantee that pesticide use will shift to safer new ones over the old ones already on the market."

As for Congress, legislation introduced last year by Representative Henry Waxman (D–CA) would have speeded up the review of old pesticides and set some firm standards for how they should be judged. The bill did not make it out of committee, but it is expected to be reintroduced next year. In the meantime, Congress simply directed EPA, in a pesticide bill approved late in the session, to complete its review of all old pesticides on the market within 9 years.

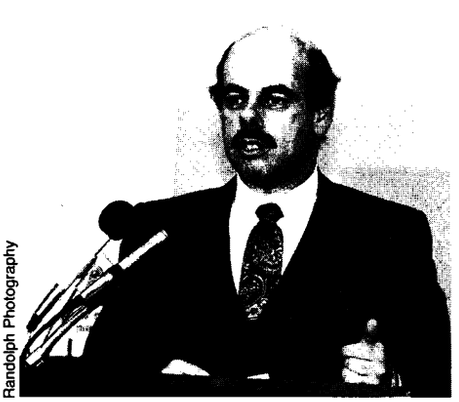
■ COLIN NORMAN

Congress Passes First AIDS Bill

In its first major legislative response to the AIDS epidemic, Congress passed a bill last week that calls for a suite of AIDS education and prevention programs, establishes a home health care program for those suffering from the syndrome, and gives to the federal health bureaucracy hundreds of new employees.

Congress has been trying to pass an AIDS policy act for several years, but the legislation always becomes bogged by skirmishes between liberals and conservatives over such contentious issues as discrimination against persons with AIDS, calls for mandatory testing, and guarantees of confidentiality for those tested for the AIDS virus.

The bill passed last week was clearly a compromise. The legislation skirts the issue of confidentiality of test results. It is also silent on the issue of discrimination against persons with AIDS or those testing positive for the virus. Many public health officials, as well as the President's AIDS commission, fear that those who need to be tested and counseled most may refuse to come forward without guarantees of confidentiality and protection.



Randolph Photography

Henry Waxman: *Pushed his bill through but had to accept compromises on confidentiality.*

The bill, which was pushed through Congress by Representative Henry Waxman (D–CA) and Senator Edward Kennedy (D–MA), is part of a package that directs about $1.2 billion toward the fight against AIDS.

Included in the bill is the addition of 780 new employees for the Public Health Service. The Secretary of the Department of Health and Human Services has 90 days to tell Congress how he plans to divvy up the slots among his various institutes.

The bill calls for broader clinical trials for AIDS drugs, and requests the National Institutes of Health to evaluate more rigorously unlicensed treatments used by AIDS patients and to expand its investigation of experimental drugs outside clinical protocols. In addition, all grant monies for AIDS research must be awarded with 9 months of announcement of the grant.

There is also $165 million for grants to the states to fund AIDS prevention programs targeted at halting the spread of the AIDS virus in the general public and in the high-risk groups. Another $105 million is earmarked for a national AIDS information campaign, which will include a toll-free hot line and will allow the government to purchase paid advertisements.

Another $100 million is given to states to counsel and test individuals for the AIDS virus. For AIDS sufferers, Congress allotted $100 million to states for the support of home health care. Finally, Congress created a national AIDS commission to monitor the epidemic and the implementation of the recommendations of the President's AIDS commission.

■ WILLIAM BOOTH

Supercomputer Centers Enter New Phase

In the next few weeks, the National Science Foundation will begin the process of deciding whether to extend funding of its five national supercomputer centers. A 5-year cycle of funding for the centers will end in 1990 and NSF will decide whether to fund the program for a subsequent 5 years.

The five centers are located at Cornell, Princeton, the University of Pittsburgh/Carnegie Mellon, University of Illinois, and University of California at San Diego. They are all submitting proposals for renewal. Applications from other institutions are not being considered.

The centers were created in response to complaints in the early 1980s that university scientists engaged in basic research requiring supercompters lacked access to the fast machines. The foundation's supercomputer program started in 1984 with a first phase in which NSF leased time for researchers at five institutions with supercomputers. The second phase, for which the five current centers were selected, was set for the 5 years from 1985 to 1990.

The centers vary in organization, but all are government-university-industry partnerships. NSF funding averages $10 million a year per center and contributions from state governments and industry amount to about the same sum. Total NSF funding for the centers this year is $54 million. NSF officials say that since 1985, the NSF portion of total funds has dropped from 60% to about 50%.

The centers are expected to serve all disciplines and have national rather than regional clienteles, but each has developed its own research specialty. Cornell, for example, emphasizes parallel processing, the Pittsburgh center is favored by biomedical researchers, and Illinois and San Diego are strong on graphics.

Cornell's supercomputer center recently received a 2-year NSF grant of $19.3 million that gives Cornell a full 5 years of funding and puts it on the same footing as the four other NSF-backed national supercomputer centers in their bid for a renewal of funding in 1990.

While NSF director Erich Bloch has indicated that NSF is disposed to continue to support the program there are no guarantees for particular centers that NSF will renew support for the next phase. All the centers complain that they are financially stretched, but as a group they have made commitments to upgrade their computing capacity that translate into fiscal optimism.

■ JOHN WALSH